

EXHIBIT A

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA)	
)	
V.)	
)	01-CR-10350-DPW
ALAN MacKENZIE, et al)	
)	
Defendants)	
)	

**Government's Memorandum Regarding RTP as a Kickback
Under Paragraph 55(b) of the Conspiracy Charged in Count I**

The government submits this memorandum to further illuminate why return to practice, when marketed as an inducement to obtain or keep Lupron business, constitutes a kickback violation, and is not protected conduct under either the affirmative defense of the statutory discount exception or the regulatory safe harbor.

I. Marketing RTP Constitutes a Violation of the Anti-Kickback Act.

The Medicare Anti-Kickback statute provides that “[w]hoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe or rebate) directly or indirectly, covertly or overtly, in cash or in kind to induce such person . . . to purchase, lease, order . . . any good or service or item for which payment may be made in whole or in part under [Medicare] . . . shall be guilty of a felony . . .” 42 U.S.C. § 1320a-7b(b)(2). Every purchaser of Lupron was able to obtain a “list price” for the drug which was lower than average wholesale price (AWP), and the spread between list price and AWP was known to the government in various ways, and assumed by the Medicare reimbursement system. What was neither assumed nor known to the government was that TAP and these conspirators gave deep discounts to doctors off that list

price and *marketed* the ensuing spread between the doctor's deeply discounted cost and anticipated Medicare reimbursement as an inducement to obtain and keep Lupron business.

There is evidence of the following in this trial: (1) that deep discounts were given to doctors off list price, (2) that TAP *marketed* the ensuing spread to obtain and keep Lupron business (Elaine Morgan's audit reviews were explicit on how the information was marketed), and (3) that TAP increased the list price (and, as a result, the published AWP in the Red Book) to increase that spread when faced with financial competition from Zoladex (Durand testimony). Thus, TAP overtly offered remuneration (RTP), that was paid indirectly (through Medicare program funds) to obtain and keep Lupron business in violation of the Anti-Kickback Act.

The Court has asked what "duty to disclose" exists in connection with these deeply discounted prices, on the part of TAP or on the part of the doctor. That duty is derived from the statutory discount exception to the Medicare Anti-Kickback statute. That statutory exception provides "(3) Paragraphs (1) and (2) shall not apply to—

(A) a discount or other reduction in price obtained by a provider of services or other entity under a Federal health care program *if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under a Federal health care program.*

42 U.S.C. § 1320a-7b(b)(3)(A). (emphasis added). Congress enacted the statutory discount exception in 1977 among a set of amendments to the Medicare Anti-Kickback Act that increased the penalty for a violation of the statute from a misdemeanor to a felony. In enacting these 1977 amendments, Congress sought to encourage medical providers to obtain common, every day discounts and price reductions where those benefits were properly disclosed and appropriately passed through to federal health care programs; Congress also sought to increase the

enforcement tools available to prevent widespread, abusive practices in the health care industry.¹

In incorporating this exception to the general prohibition of the Anti-Kickback Act, Congress recognized the value of discounts, and the benefit that having providers purchasing at a discount could mean for the Medicare program. As noted by Judge Keeton:

[T]he discount exception makes good sense. The statute was passed to curtail fraud and abuse in Medicare and Medicaid reporting, in particular. It was passed to prevent health care service and good suppliers and providers from depriving the federal and state health care subsidy system of the benefits that a free market for health care services and goods can provide. By allowing for suppliers and providers of health care service and goods to compete with one another in limited forms, the statute strikes a balance: on the one hand, it provides for some of the benefits of a market economy by encouraging limited forms of price competition; on the other hand, it deters and *penalizes other types of conduct that would lower the cost of some health care services and goods for some suppliers and providers but would not pass on that lowered cost to the federal and state health systems or to its patients.*

United States v. Shaw, 106 F. Supp. 2d 103, 115 (D. Mass. 2000). Thus the statutory discount exception means that suppliers (such as TAP) and providers (such as physician customers of

¹In 1977, Congress perceived pervasive fraud and abuse in the health care industry with regard to the Medicare and Medicaid programs:

In recent years, numerous hearings, studies, and investigations undertaken by this committee and other committees of the Congress, the General Accounting Office, and other Federal and State agencies have demonstrated that there exist, to a disturbing degree, fraudulent and abusive practices associated with the provision of health services financed by the medicare and medicaid programs... [Fraud] cheats taxpayers who must ultimately bear the financial burden of misuse of funds in any government-sponsored program. It diverts from those most in need, the nation's elderly and poor, scarce program dollars that were intended to provide vitally needed quality health services. The wasting of program funds through fraud also further erodes the financial stability of those state and local governments whose budgets are already overextended and who must commit and ever-increasing portion of their financial resources to fulfill the obligations of their medical assistance programs.

H.R. Rep. No. 393(II), 95th Cong., 2d Sess., reprinted in 1977 U.S. Cong. Code & Admin News 3039, 3046-47.

TAP) have a “duty to disclose” because they must “properly disclose” and “appropriately reflect” their discounts, to meet this exception to the prohibitions of the Anti-Kickback statute.

II. Meeting the Statutory Discount Exception is an Affirmative Defense.

The statutory discount exception is an affirmative defense that the defendants had the burden to prove at trial.

It is a well-established rule of statutory construction that an exception set forth in a distinct clause or provision should be construed as an affirmative defense and not an essential element of the crime. United States v. Riviera, 183 F.3d 367, 370-71 (5th Cir. 1999); McKelvey v. United States, 260 U.S. 353, 357 (1922)(“By repeated decisions it has come to be a settled rule in this jurisdiction that an indictment or other pleading founded on a general provision defining the elements of an offense . . . need not negative the matter of an exception made by a proviso or other distinct clause . . . and that it is incumbent on one who relies on such an exception to set it up and establish it.”); United States v. Chodor, 479 F.2d 661, 663 (1st Cir.)(citing McKelvey), cert. denied, 414 U.S. 912 (1973); United States v. Ramzy, 446 F.2d 1184, 1186 (5th Cir.), cert. denied, 404 U.S. 992 (1971); United States v. Roya, 574 F.2d 386, 391 (7th Cir. 1978)(“An indictment founded on a general provision in a statute need not negative an exception made by a proviso or other distinct clause, whether in the same section or elsewhere.”); Chin Gum v. United States, 149 F.2d 475, 479-80 (1st Cir. 1945).²

²In United States v. Vuitch, 402 U.S. 62 (1971), the Supreme Court noted that where an exception was incorporated in the enacting clause of the statute, the burden was on the prosecution to plead and prove the defendant was not within the exception. Id. at 70. Here, the discount exception of the Medicare Anti-Kickback Act was not incorporated in the enacting clause of illegal remunerations set forth in 42 U.S.C. § 1320a-7b(b)(1) and (2), but was set forth as one of five separately enumerated exceptions, so the prosecution bears no such burden here.

In interpreting criminal statutes, courts routinely hold that separately cast exceptions are affirmative defenses. For example, in interpreting the federal machine gun statute, 18 U.S.C. § 922(o), the Fifth Circuit held that where the statute prohibited unlawful possession of a machine gun but contained an exception in a separate subsection for lawful possession prior to the statute's effective date, the exception was an affirmative defense. United States v. Gonzales, 121 F.3d 928, 936-37 (5th Cir. 1997), cert. denied, 118 S.Ct. 726 (1998); accord United States v. Just, 74 F.3d 902, 904 (8th Cir. 1996); see also United States v. Steele, 147 F.3d 1316, 1318-20 (11th Cir. 1998)(joining Third, Sixth, and Seventh Circuits in analogous interpretation of 21 U.S.C. § 841, regarding distribution of controlled substances).

In United States v. Chodor, 479 F.2d 661 (1st Cir. 1973), the First Circuit held that an exception set forth in a separate proviso within the operative definition of the crime of counterfeiting securities in 18 U.S.C. § 474 was an affirmative defense. The Court concluded that the Government was not required to offer evidence on the issue of whether the defendant was in possession of obligations "under authority from the Secretary of the Treasury or other proper official" where the statute provided in pertinent part:

Whoever has in his possession or custody, *except under authority from the Secretary of the Treasury or other proper office*, any obligation or other security made or executed, in whole or in part, after the similitude of any obligation or other security issued under the authority of the United States, with intent to sell or otherwise use the same . . .

18 U.S.C. § 474 (emphasis added). The First Circuit reasoned that the exception in the statute was an affirmative defense which the defendant was required to set up and establish. Id. at 663; accord, United States v. Green, 962 F.2d 938, 941 (9th Cir. 1992)(following "[t]he well-established rule . . . that a defendant who relies upon an exception to a statute made by a proviso or distinct clause, whether in the same section of the statute or elsewhere, has the burden of

establishing and showing that he comes within the exception.”). The Government has neither the obligation to allege an exception in the indictment nor the burden of going forward on the issue.

United States v. Hester, 719 F.2d 1041, 1043 (9th Cir. 1983).

The discount exception in the Medicare Anti-Kickback Act is set forth in a separate subsection containing five different exemptions to the illegal remuneration defined in 42 U.S.C. § 1320a-7b(b)(1) and (2). The plain language of subparagraph (b)(3) of the Medicare Anti-Kickback Act is written as an exception to the crime of illegal remunerations stating “[p]aragraphs (1) and (2) shall not apply to—.” This language is nearly identical to the phrasing of the statute prohibiting possession and transfer of a machine gun, 18 U.S.C. § 922(o), “[t]his subsection does not apply with respect to—,” which both the Fifth and Eighth Circuits held to be an affirmative defense to be set up and proved by the defendant at trial, not an element of the offense that must be charged in the indictment. United States v. Just, 74 F.3d 902, 904 (8th Cir. 1995); United States v. Gonzales, 121 F.3d 928, 936-37 (5th Cir. 1997). Moreover, the term “remuneration” in the Medicare Anti-Kickback Act is broadly defined to include “any” remuneration. The narrowly drawn discount exception, like the other enumerated statutory exceptions, identifies a specifically defined payment practice.

Thus, the issue of whether or not the overt acts involving the marketing of return to practice to obtain and keep Lupron business falls within the statutory discount exception is an affirmative defense that the defendants had the burden to prove at trial.

III. The Defendants Have Not Met the Burden of Proving the Affirmative Defense.

It was overwhelmingly proved at trial that TAP and these co-conspirators marketed RTP, encouraging physicians to charge AWP and not their discounted cost, inducing physicians to buy

Lupron by promising that the physician could pocket more money by buying Lupron than buying Zoladex. McAlpine testified that the “financial sell” was introduced in 1993, and various witnesses testified about being taught how to market RTP to doctors. In the Big Mac Attack in 1997, TAP referred to RTP as its “checkbook” and, as the evidence showed, those checks were drawn on the Medicare program. Thus, TAP and these conspirators actively sought to prevent the Medicare program from obtaining the benefit of the discounted prices on Lupron that they provided to physicians. Thus, these defendants did not establish any evidence, and can not claim, the benefit of the affirmative defense provided in the statutory discount exception to the Medicare Anti-Kickback Act because the discount was not “appropriately reflected” in the charges to the Medicare program. The purpose of the statutory discount exception was to ensure the Medicare program benefited from discounts to providers. The conduct of these co-conspirators was expressly designed to *prevent* Medicare from obtaining the benefit of those discounts, ensuring ever increasing profits to the doctor for buying Lupron over the cheaper and equally effective alternative GNRHa agonist.

IV. The Defendants Have Not Met the Requirements of the Regulatory Discount Safe Harbor.

Pursuant to enabling legislation in 1987, the Secretary of Health and Human Services clarified the discount exception in 1991 and again in 1999, promulgating the regulatory discount safe harbor discussed below. In enacting enabling legislation for the safe harbors, Congress charged HHS to clarify which, if any, payment practices should be protected, through a process that included a “determination of the scope of the statute and decisions as to how to draft the safe harbor provisions so that they protect only non-abusive relationships.”

The discount safe harbor expressly provides that where a seller (such as TAP) provides a

discount to a buyer (such as a physician customer who submits his own reimbursement claims to Medicare), the seller must

fully and accurately report such discount on the invoice, coupon or statement submitted to the buyer; inform the buyer in a manner reasonably calculated to give notice to the buyer of its obligations to report such discount and to provide information upon request under paragraph (h)(1) of this section; and refrain from doing anything that would impede the buyer from meeting its obligations under this paragraph.

42 C.F.R. § 1001.952(h)(2)(iii)(B). In this trial, the evidence showed that physicians who did not buy sufficient quantities of Lupron to have a contract with TAP did not receive "notice" of their "obligations to report such discount" until July 1998 when the information was finally added to TAP's invoices. (e.g. 310.18 - Dr. Hwong's invoices). For Phoenix Urology, the language regarding a disclosure obligation, which Liz Dunst explained was necessary in the summer of 1996, was not added until the 1997 contract. Moreover, the evidence showed that TAP took deliberate steps to "impede" the buyer from meeting its obligations by (1) actively telling doctors to hide their actual prices in the Big Mac Attack, and by (2) providing "account reviews" or "reimbursement audits" that directed physicians to bill the AWP, rather than reporting a discount, which duty derives from the Medicare Anti-Kickback Act.

V. If the Court Finds Some Evidence Presented by Defendants of Meeting the Regulatory Safe Harbor, the Issue Should be For the Jury to Decide.

If the Court believes that some evidence has been presented on this affirmative defense, then the issue should be for the jury. The Government believes that no discount safe harbor instruction is warranted because the discounts were not "appropriately reflected" or "disclosed" given the way RTP was marketed by TAP. However, if some instruction is given, the government believes that the jury should be informed that the safe harbor can only be considered

after they find evidence that notice was affirmatively provided to the doctors by TAP.

Respectfully submitted,

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By:

/s/
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Dated: June 24, 2004

Certificate of Service

I hereby certify that this pleading has been served by e-mail.

/s/
Susan G. Winkler

EXHIBIT B

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Defendants' Exhibit
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1 THE CLERK: This Honorable Court is now in
2 session. Please be seated.

3 THE COURT: One specific question: Have the
4 defendants filed their jury instructions? I just
5 haven't seen them on the --

6 MR. KETTLEWELL: No. Actually, they haven't
7 been filed, Your Honor. We're trying to file one set
8 with all 10 people and we've circulated a draft and I
9 think we're very close to having agreement on all of
10 them.

11 THE COURT: Okay. I just didn't know if there
12 was something --

13 MR. KETTLEWELL: They should be here -- they
14 will be filed today.

15 THE COURT: All right. Now, let me outline
16 the order of battle. Ms. Greenberg -- because the
17 Government asked what the order is that we'll go through
18 this, I think the way in which I'd like to do it is
19 start with the broad objects of the conspiracy motions
20 to frame the legal issues here. And specifically, I
21 want to start with defraud the Government object, then
22 the sampling law issues, and then I'll talk a little bit
23 about an anti-kickback. But I think at that point, I'm
24 going to want to start talking very specifically about
25 particular defendants.

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1 I would hope that -- there's a large body of
2 material that was filed yesterday which I've tried to
3 get through it, but I haven't, I think, fully absorbed
4 it. But it's very helpful, I think, in framing the
5 issues here. And, so, I'm going to use that as the
6 agenda for the Government to respond in specific ways.

7 What I think I anticipate happening is that I
8 will be asking for specific citations to specific

9 transcript and to documents that have been introduced.
10 And we can use the screen to do that so everybody gets
11 to see it at the same time. That's my hope, anyway.
12 Now, let me turn to this question of
13 defrauding the Government. I framed it -- in just my
14 kind of things to think about yesterday -- as what's the
15 duty to disclose? There are terms of art involved, so
16 that's a little misleading. But let me put it a
17 different way. This is clearly an area in which the
18 Federal Government and its various agencies has
19 been struggling to develop a coherent pattern for
20 reimbursement. And for a variety of reasons, it's hit
21 on the idea about average wholesale price. And
22 depending on the administration, people at OMB think
23 that there's too much paperwork in trying to do a real
24 evaluation of what these prices are. And people who are
25 in the pharmaceutical business aren't really interested

1 in having the Government get too intrusive. And, so,
2 they're perfectly happy if the Government is not
3 directly involved in administering the prices except
4 beyond the AWP. So, it's a yeasty area. But I'm not
5 certain that there is any criminal violation for people
6 to pursue their business in light of a structure that is
7 as open-textured as this unless they are either lying to
8 the Government in their presentation or they have some
9 duty to disclose to the Government some aspect of the
10 business. That, it seems to me, is at the core of what
11 the defraud clause in this setting asks for. And, so, I
12 guess I want to understand from the Government what it
13 was that they were supposed to do, not what would have
14 been nice for them, what would have been public-spirited
15 for them to do, but what they were obligated to do.
16 MR. LOUCKS: Your Honor, thank you. I'll try
17 to address the Court's questions.
18 Our prong (a) is predicated on two things, one
19 of which is conspiring to defraud to obtain money or
20 property. The second is conspiring to thwart the
21 operations of the programs. Providing a kick- -- I
22 mean, there have been a number of cases that have
23 approved conspiring to defraud theories against the
24 Medicare and Medicaid programs by paying kickbacks.
25 The cases that have not approved it have been where

1 there has been no showing of a loss or an increased
2 cost.
3 THE COURT: So you're saying that it's simply
4 a duplication of the anti-kickback statute?
5 MR. LOUCKS: No. Because the anti-kickback

6 statute -- there are different elements in both.
7 The anti-kickback statute does not require proof of
8 loss. Conspiring to defraud requires proof of
9 conspiring to defraud to obtain money or property.
10 That's not a part of the anti-kickback statute.
11 THE COURT: So you've got to prove even more
12 for there to be conspiracy to defraud?
13 MR. LOUCKS: You have to prove an intent to
14 obtain money through the course of --
15 THE COURT: Right. But you've got to prove
16 something more?
17 MR. LOUCKS: Yes.
18 THE COURT: All right. So, what do you need
19 it for?
20 MR. LOUCKS: What do we need it for in this
21 case?
22 THE COURT: Right. I mean, it seems
23 replicative. As you've described it, the anti-kickback
24 statute is a lesser-included offense of defrauding the
25 Government on this prong.

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1 MR. LOUCKS: On this prong. There are
2 different intent aspects as well.
3 THE COURT: Yes. The intent is even easier on
4 the anti-kickback statute.
5 MR. LOUCKS: Actually, I thought it was the
6 other way around, Judge.
7 But our view is this, also, is that there
8 has been substantial proof of an intent to provide
9 inducements to get around reporting obligations on best
10 price.
11 THE COURT: Well, I'll get to that in a
12 minute. That's thwarting as far as I'm concerned.
13 Now I want to deal with this parallel kickback
14 theory. And I want to understand why it is that a jury
15 should be instructed on something like this that just
16 means another set of moving parts. You say that you've
17 got to prove loss. No, you don't have to do that with
18 the anti-kickback statute. Okay. So, as I said,
19 lesser-included offense. You say there is some
20 difference in intent. I'm not altogether sure.
21 MR. LOUCKS: I'm not sure, as a practical
22 matter, one could explain to a jury a difference in
23 intent between prong (a) and prong (b) where the
24 underlying conduct for both includes payment kickbacks.
25 We actually discussed this amongst ourselves, that

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1 there is a parallel between the two, that it would

2 enhance or potentially cause some juror confusion as to
3 what is the appropriate intent on (b) versus the
4 appropriate intent on (a).

5 THE COURT: Right. But that just takes it one
6 -- that takes it to a broader level of generality. This
7 is (a)(1). And it's the parallel to the anti-kickback
8 statute. Why do you need it? Even assuming that you
9 can get it, why do you need it?

10 MR. LOUCKS: Your Honor, I'm not sure that we
11 do, frankly. We talked about this at length yesterday.
12 Cases never play out of the courtroom as one --

13 THE COURT: I understand that. That's why I
14 denied the motions to dismiss. And I wanted to see how
15 this worked out so I can understand more fully. Now I
16 think I understand it more fully. And I don't see this
17 aspect of it having any value, except the potential for
18 confusion.

19 MR. LOUCKS: Yes, Your Honor. We actually
20 discussed yesterday as our appropriate thing to do was
21 to come in here and say we don't need it. The case is,
22 we think, fairly well-established for a jury on prong
23 (b) on the kickbacks; that there is a duplication in the
24 degree between the first part of (a) and (b), although
25 there are different elements. The Government suffered a

1 loss through the providing of inducements to cause
2 doctors to prescribe a more expensive product. But as
3 the case tried, as the witnesses testified -- and people
4 didn't testify in many respects like they Grand Juried,
5 if you will, that our view yesterday -- when we were
6 discussing this and looking at it before we had seen any
7 of the materials from the defendants -- was that there
8 is a jury confusion that will come from trying to
9 explain --

10 THE COURT: Well, I agree with that. So, this
11 isn't "mother, may I", but I assume that the Government
12 is prepared to go forward simply on the PDMA and the
13 anti-kickback?

14 MR. LOUCKS: Yes. If I can just talk with my
15 colleagues for a second, I think that's right.

16 THE COURT: Yes.

17 MR. LOUCKS: Your Honor, the only issue we
18 have -- and I'm not sure it's an issue -- is that we've
19 proved as a part of the kickbacks a motive to cheat on
20 Government pricing, we believe, both with respect to
21 Kadia and the testimony by Pelagalli that there was a
22 discussion that he was getting the best price and
23 couldn't go lower on the price. Pelagalli didn't know
24 that it was the best price.

25 THE COURT: Well, I'm prepared to explore that

1 if you want to keep going on this defraud the government
2 count. I happen to think that it's evidentiary on the
3 other issues. It's not something that I'm likely to
4 exclude.
5 MR. LOUCKS: That's our point.
6 THE COURT: I mean, intent is a major part of
7 the case. So, this goes to the intent of the defendants
8 with respect to how they deal with their various
9 marketing techniques, including remuneration.
10 MR. LOUCKS: And that's our point, Your Honor.
11 So, no, we're not pursuing that to maintain prong (a).
12 We think the case is all about how the proof came in
13 and there has been a lot of duplication between prong
14 (a) and prong (b). And the objects are different:
15 Different crimes, different elements. But we don't have
16 an issue with the case going forward on prong (b).
17 THE COURT: All right. Well, on that basis,
18 it's my intention not to instruct the jury with respect
19 to conspiracy to defraud the United States. So, that
20 deals with that portion of the case.
21 MR. KETTLEWELL: Your Honor, at the
22 appropriate time, can we be heard on this best price
23 motive stuff?
24 THE COURT: Well, I do want to talk about it a
25 bit. But I thought I would talk about it in terms of

1 what kinds of things to talk about in the closing
2 argument, but maybe this is the time to talk about it.
3 The way In which I was looking at this --
4 and, of course, I'm here to learn, not merely to instruct --
5 was I had some considerable difficulty seeing this as a
6 conspiracy to defraud kind of case. And the proof --
7 with respect to a best price violation, straight best
8 price violation, seemed to me to be rather thin,
9 perhaps diaphanous, but, you know, talking up
10 decision-makers at HMOs about why you can't go any
11 farther down in your price and saying we've got this
12 best price obligation that we've got to deal with. That
13 tells you something about the way in which they market,
14 but I don't think it proves a best price violation and I
15 have considerable thought and concern about that. So,
16 do you intend to argue that this was independently a best
17 price violation when you get to --
18 MR. LOUCKS: No, no. I intend to argue that
19 one of the reasons they did things off price, off
20 contract, was because they were schooled in the notion
21 that there is a best price floor precisely as Ms.
22 Swirski said. "If I go any lower, we're going to have
23 to affect our government contract pricing." But I
24 think that also demonstrates quite a bit about her
25 intent, that we're going to have to do it on --